

## REMARKS

Claims 1-7, 9, 16, 26-27, and 32-38 were pending in the application. By this amendment, claims 39 and 40 have been added. No claims have been amended or cancelled.

The following remarks are in response to the grounds for rejection of claims set forth in the Office Action.

### I. Claims Rejected Under 35 U.S.C. § 103

Claims 1, 3-7, 9, 26-27, and 32-38 were rejected as being unpatentable over Koike et al. (USP 6,056,760) in view of Gannoe et al. (USP 6,746,460), Laufer et al. (US Pub. No. 2004-0194790), and Saadat (USP 7,186,262). Claims 2 and 16 were rejected as being unpatentable over Koike, Gannoe, Laufer, and further in view of Matsui et al. (USP 6,352,503). Except for the addition of the Saadat patent, the rejections are on similar grounds to those included in the prior Office Actions mailed on September 19, 2006 and April 17, 2007.

In Applicant's prior Responses, filed February 20, 2007 and June 19, 2007, Applicant presented Remarks supporting Applicant's position that the rejections of all claims should be withdrawn because the Office Action failed to establish a prima facie case of obviousness of the claims. In the current and prior Office Actions, the Examiner acknowledged those Remarks, but deemed them unpersuasive. Applicant appreciates the Examiner's careful consideration of these issues. Applicant also strongly disagreed with the Examiner's responses, and continued to maintain that the combinations of the patents and publications relied upon to reject the claims would not have been obvious to a person of ordinary skill in the art, for each of the reasons set forth in Applicant's prior responses.

In its prior responses, Applicant expressly reserved its right and expressed its intent to pursue allowance of those claims rejected based upon these combinations of references, through appeal of their rejection if necessary. The purpose of the present response is to clarify those issues for appeal, should the Examiner maintain the rejections of the claims. In particular, claims 1, 3-7, 9, 26-27, and 32-38 were not amended, and so remain in the same form as they were prior to the pending Office Action. New claim 39 corresponds with claim 32 prior to its amendment in Applicant's response dated June 19,

2007. New claim 40 corresponds substantially with claim 32 in its prior form, and adds that the tissue fold is held with a “tissue grasper” that is associated with the catheter.

Response as to All Rejected Claims

As an initial matter, Applicant notes that the varied subject matter contained in the references relied upon by the Examiner is itself indicative of the nonobviousness of the claims at issue. The otherwise unrelated devices, systems, and methods described in these several references are collected and combined in a manner that can only be the result of improper hindsight reconstruction based upon the claims at issue. Furthermore, and relatedly, the Examiner’s attempts to set forth reasons why a person of ordinary skill in the art would have been motivated to combine these references in the manners set forth in the Office Action are insufficient to set forth a prima facie case of the obviousness of the claims.

For example, the primary reference relied upon in each of the rejections – the Koike patent – describes an intracardiac suturing device and method. The Examiner correctly describes several of the features disclosed in the patent that are comparable to elements in the present claims (e.g., a delivery catheter, a needle or piercing element, anchors, sutures, ejecting anchors from a distal tip of a piercing element). The Koike patent, however, contains no teaching or suggestion that its device or method (or any portions thereof) should be combined with the devices and methods described in any of the other cited references. Nor is there any common sense or other reason why such combinations would be made. The Gannoe patent, for example, discloses a space-occupying device for implanting into the gastrointestinal system of a patient. The Laufer publication discloses an instrument for reconfiguring tissue in the vicinity of the gastroesophageal junction. The devices and methods disclosed in these references are intended for distinct purposes (suturing / device implantation / tissue reconfiguration) in distinct parts of the body (heart / stomach / gastroesophageal junction). The Koike device is introduced to the patient’s heart through the vasculature (see col. 5, ll. 32-55), whereas the Gannoe and Laufer devices are introduced to the patient’s stomach via the esophagus. The Examiner provides no explanation as to why a person of ordinary skill in the art would have been motivated to combine selected portions of the devices and

methods disclosed in these disparate references, much less why such a person would have completely ignored the portions of those references that teach away from such a combination.

For example, the devices disclosed in the three references are physically incompatible with one another, making the combination suggested by the Examiner even less likely to have occurred to a person of ordinary skill in the art. The catheter of the Koike device, which is transported through the vasculature, will necessarily have a much smaller diameter than is required of either the Gannoe or Laufer devices. There is, therefore, no way for the Koike device to accommodate the features of the Gannoe or Laufer devices without fundamentally changing the basic principle under which the Koike device is intended to operate. As another example, the piercing member of the Koike device is operated using a push rod extending through a lumen extending the length of the catheter. There is no comparable lumen or push rod provided in either of the Gannoe or Laufer devices. The Laufer device is instead actuated using pull cables. Any modification of one device to include features of the other – which is the premise of each of the Examiner's obviousness contentions – would carry with it the need to either modify (in some unspecified way) or abandon the existing actuation mechanism of the first device. These are but a few of the incompatibilities between these devices; there are many more. On the other hand, there is nothing at all that would suggest to a person of skill in the art that the devices could possibly be combined in the manner suggested by the Examiner.

The Examiner has previously stated that the test for obviousness is not whether the features of a secondary or tertiary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. Applicant agrees with the Examiner's statement of the law, but the statement both misses Applicant's point and fails to support the Examiner's obligation to present a prima facie case of obviousness. Applicant's point, instead, is that the combined teachings of the Koike, Gannoe, and Laufer references would not have led one of ordinary skill in the art to Applicant's claimed invention, for all of the reasons set forth above.

In order to support a rejection of claims for obviousness under section 103, the Examiner is obliged to provide an explanation why one of ordinary skill in the art at the time the invention was made would have been motivated to combine the teachings of the cited references. M.P.E.P. § 706.02(j). In this case, each of the following precludes the Examiner from doing so: (1) the distinct nature of the devices and methods described in the cited references, (2) the incompatibility of those devices and methods, and (3) the fact that the modifications suggested by the Examiner would not allow the devices and methods described in each of the references to function in its intended manner. Accordingly, the Examiner has failed to establish a prima facie case of the obviousness of the rejected claims. The rejection of these claims should be withdrawn, and the claims allowed.

Rejection of Claims 1, 6-7, and 38:

In the rejection of claims 1, 6-7, and 38, the Examiner states that the Koike patent discloses several of the device elements and method steps recited in the claims, but notes the following that is missing from Koike:

Koike et al. discloses the claimed device except for a stabilization device disposed at the distal end, engaging the stabilization device to a tissue wall of the gastrointestinal lumen before advancing the catheter through the tissue wall, and advancing the delivery catheter and needle into the gastrointestinal lumen, or tract of a patient, and translating a fastener over the suture whereby a tension force is created on the suture and said tissue fold is maintained.

The Examiner then notes that the Gannoe patent teaches delivering a delivery catheter into the gastrointestinal lumen “in order to reduce the amount of food desired by patients who may be obese.” But the Examiner completely ignores that Gannoe’s device and method for achieving this objective – indeed, the primary focus of the Gannoe patent – is to provide a space-occupying device to be implanted into the stomach. Nowhere does Gannoe teach or suggest using anchors disposed within a tissue piercing element for any purpose. Similarly, the Koike patent has nothing to do with treating obesity, or with any procedures to be performed within the gastrointestinal system. Nonetheless, the Examiner concludes:

It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a tissue piercing element into the gastrointestinal lumen, as taught by Gannoe et al., to Koike et al. in order to aid obese patients in managing the amount of food desired and eaten.

Applicant strongly disagrees with the Examiner's rationale and conclusion, and respectfully submits that the Examiner has failed to identify any teaching that would have motivated a person of ordinary skill in the art to combine the Koike and Gannoe patents in the manner suggested.

The failure is magnified by the Examiner's attempt to combine the Laufer publication's teaching of the use of a stabilization device with the combined teachings of the Koike and Gannoe patents. The Examiner states that the combination would have been obvious:

since it was known in the art that tissue piercing elements may injure or tear tissue from translating or puncturing, as well as withdrawing, retracting movement if the tissue is not stabilized and a stabilization device may prevent injury to the tissue.

Without conceding the Examiner's contention that this use of stabilizing devices was generally known for this purpose, the fact remains that there is no teaching or suggestion as to how the Laufer stabilization device would possibly be combinable with the Koike delivery catheter in view of the system incompatibilities discussed above, much less how all of the foregoing is then combined with the Gannoe device and method. Once again, Applicant's contention is not that physical and operational incompatibility is the test for obviousness; instead, Applicant contends that the many and substantial differences between these devices negates the Examiner's contention that a person of ordinary skill in the art would have been motivated to combine them in the manner suggested.

Finally, the Examiner also combines the Saadat patent's teaching of the use of a collar fastener that is slid over a suture to maintain a tissue fold held by the suture. The Examiner states that the combination would have been obvious:

Since Koike et al. discloses that the suture threads T1 and T2 are ligated together by a knot (Figure 10), it would have been obvious to one of ordinary skill in the art to modify Koike et al. by replacing the knot with a fastener or crimp so that the tension is maintained and fastener that may be translated over the suture after tissue has been approximated to adjust tension, as taught by Saadat.

In this instance, the Examiner has only stated the objectives and advantages of the device described in the Saadat patent. Nowhere is there any support for the contention that modifying the Koike device with the Saadat fastener would have been obvious. This is insufficient to establish a prima facie case of obviousness.

In summary, the Examiner has failed to sufficiently identify any legitimate teaching as to why a person of ordinary skill in the art would have been motivated to combine the Koike, Gannoe, Laufer, and Saadat references in the manner suggested by the Examiner to reject the claims. Accordingly, the Examiner has failed to establish a prima facie case of the obviousness of claims 1, 6-7, and 38. The rejection of these claims should be withdrawn, and the claims allowed.

Rejection of Claims 26, 32, and 35:

In the rejection of claims 26, 32, and 35, the Examiner again relies on the combination of the Koike and Gannoe patents, stating:

It would have been obvious to one of ordinary skill in the art to provide the step of creating a tissue fold, as taught by Gannoe et al., to Koike et al., since it was known in the art that obesity may be treated by forming folds in the gastrointestinal lumen which aids obese patients in managing the amount of food desired and eaten.

Without conceding the Examiner's contention concerning knowledge in the art, the fact remains that the Koike patent has nothing to do with "forming folds in the gastrointestinal lumen" or any other methods relating to obesity treatment. There is nothing in either of these references, or in the art in general, that provides any motivation for a person of ordinary skill in the art to combine these references in the manner suggested by the Examiner. The rejection of claims 26, 32, and 35 should be withdrawn.

Rejection of Claims 3-5, 9, 27, 33-34, 36, and 37:

The Examiner's rejection of claims 3-5, 9, 27, 33-34, 36, and 37 were based upon the same combinations of Koike, Gannoe, and Laufer discussed above. Accordingly, these rejections should be withdrawn for the reasons set forth above.

Rejection of Claims 2 and 16:

Claims 2 and 16 were rejected based upon the same combination of Koike, Gannoe, and Laufer, in further view of the Matsui patent. The Examiner did not assert the Saadat patent against claims 2 and 16, despite the fact that these claims depend from claims 1 and 6, respectively, which recite translating or advancing a fastener over the suture.

As to addition of the Matsui patent, Applicant does not disagree with the Examiner's description of that patent. However, the Matsui patent does not supply any teaching or suggestion that would have motivated a person of skill in the art to combine the four references in the manner suggested by the Examiner. Accordingly, these rejections should also be withdrawn.

For these reasons, Applicant submits that the present claims contain subject matter that is patentable over the prior art. Applicants request withdrawal of the rejections of these claims. A Notice of Allowance is requested.

II. New Claims 39 and 40

As noted above, claim 39 is identical to claim 32 as presented prior to its amendment in Applicant's paper filed on June 19, 2007. Claim 40 is similar, but also recites a "tissue grasper" to perform the holding step. These claims are patentable over the cited art for the same reasons set forth above.

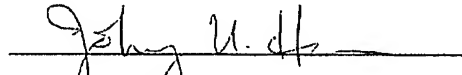
Amendment and/or cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented. Similarly, unless explicitly stated, nothing contained or not contained in this paper should be construed as an assent to any of the Examiner's stated grounds for rejecting the claims, including specifically the Examiner's characterization of the teachings of the cited art and the Examiner's contentions that any combinations of cited art would have been obvious. Rather, the present amendments to the claims and Remarks are an attempt to expedite allowance and issuance of the currently pending claims. No new matter has been added.

### CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections and pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the appropriate fee and/or petition is not filed herewith and the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with this filing to **Deposit Account No. 50-3973** referencing Attorney Docket No. **USGINZ02112**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,



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